

**ELECTRONICALLY FILED**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of:	Barbara Ensoli	Confirmation No.:	9400
Application No.:	09/555,534	Art Unit:	1648
Filed:	November 30, 1998	Examiner:	Humphrey, Louise Wang Zhiying
For:	HIV TAT, OR DERIVATIVES THEREOF FOR PROPHYLACTIC AND THERAPEUTIC VACCINATION	Attorney Docket No.:	11340-003-999

**STATEMENT OF THE SUBSTANCE OF THE INTERVIEWS**

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Commissioner for Patents  
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Sir:

In accordance with 37 C.F.R. § 1.133(b), Applicant presents this Statement of the Substance of the two interviews held with the United States Patent and Trademark Office in connection with the above-identified application.

**INTERVIEW ONE**

On December 10, 2009, Examiner Humphrey, Supervisory Patent Examiner ("SPE") Mondesi, and Adriane M. Antler and Ann Chen, attorneys for Applicant, had a telephonic interview regarding the above-identified application.

Dr. Antler first explained why the Fourth Magnani Declaration should be entered, since Applicant had made a sufficient showing under Rule 116 as to why it should be entered, *i.e.*, why it was necessary and not earlier presented (as detailed in the Response Under 37 C.F.R. § 1.116 ("Response") filed October 29, 2009). SPE Mondesi agreed to look at the issue and see what could be done.

Dr. Antler next addressed the substantive issues in the Office Action, making the points essentially as set forth in the Response filed October 29, 2009 in support of Applicant's position that the claimed invention is nonobvious, to wit:

(1) the recitations of “biologically active” and “pharmaceutically acceptable for administration to a human” (termed hereinafter “PAAH”) impose certain structural requirements on the claimed subject matter (which Dr. Antler explained);

(2) the procedures taught by Chang *et al.* result in HIV Tat protein-containing compositions that are contaminated with substances (acetonitrile, TFA, and PMSF), that render the composition not PAAH, as evidenced by the First and Second Gad Declarations;

(3) there was no motivation in the art to remove TFA and PMSF from the Chang *et al.* compositions, because of the teaching away in the art from the therapeutic use of biologically active HIV Tat protein due to biologically active HIV Tat protein’s believed harmful health effects (citing the Third Ensoli Declaration);

(4) there was skepticism in the art regarding such therapeutic use (citing the Third Ensoli Declaration);

(5) unexpected results were obtained with the claimed invention, *i.e.*, the data shows that biologically active HIV Tat protein was safe and well tolerated, and had treatment efficacy (citing the Second Ensoli Declaration);

(6) the use of the Sumner-Smith method to remove TFA, whether before or after the lyophilization and resuspension of Chang *et al.*, is expected to destroy the biological activity of HIV Tat protein (citing the Third and Fourth Magnani Declarations);

(7) if one skilled in the art were so motivated, one could avoid the use of PMSF using methods routine in the art as described in the First Magnani Declaration and the Supplemental Magnani Declaration, but one in the prior art would not be motivated to do so in view of the teaching away in the art from *in vivo* use of biologically active HIV Tat protein (see number 3 above); and

(8) the Gu reference discloses a phase separation method that is an improved method for removing acetonitrile, but that is inapplicable to HIV Tat protein; the problem of residual acetonitrile and TFA remains.

Dr. Antler also noted to Examiner Humphrey and SPE Mondesi, so that they could have this corrected, that three of the declarations Applicant had filed in the past were miscoded in PAIR: the First Magnani Declaration, the Second Ensoli Declaration and the Third Ensoli Declaration.

In response to SPE Mondesi’s question about the nature of the HIV Tat protein, Ms. Chen directed him to page 2, lines 14-15 of the specification.

SPE Mondesi stated that he and Examiner Humphrey would meet with a quality assurance specialist at the United States Patent and Trademark Office to go through the above issues and determine what they will do.

### INTERVIEW TWO

On December 18, 2009, Adriane M. Antler, Attorney for Applicant, telephoned SPE Mondesi to discuss the Interview Summary dated December 15, 2009 that had been mailed by the United States Patent and Trademark Office. Dr. Antler expressed her confusion over the remarks on the Continuation Sheet of the Interview Summary, since the remarks did not address what had been argued at the interview of December 10, 2009 by Attorneys for Applicant (or what had been argued in the prosecution history of the application). In particular, regarding the Interview Summary statement that

“Applicants never proffered any objective evidence or experimental data showing side-by-side comparison of the prior art Tat protein with the claimed Tat protein to support the assertion that the prior art Tat protein composition is not the same or does not have the biological activity of the claimed Tat protein composition.”

Dr. Antler stated that (i) Applicant never argued that the Chang *et al.* Tat composition did not contain biologically active HIV Tat protein, only that the composition was contaminated with “toxic” substances, *i.e.*, that rendered the composition not pharmaceutically acceptable for administration to a human (“PAAH”); (ii) Chang *et al.* itself teaches that those substances [*e.g.*, PMSF] are present in the composition; and (iii) Applicant had provided evidence by way of the declaration of a toxicologist that those substances are “toxic” (with attached publications as evidence), which toxicity had never been disputed by the United States Patent and Trademark Office. SPE Mondesi responded that whatever declarations Applicant had filed were insufficient evidence, and were merely opinions.


Regarding the statement in the Interview Summary dated January 15, 2009 that the declaration filed after final would “NOT be entered because the declaration does not place the application in condition for allowance,” Dr. Antler explained that Applicant had argued that the Fourth Magnani Declaration should be entered *because it satisfies Rule 116, i.e.*, because Applicant had explained why it was necessary and not earlier presented. SPE Mondesi’s response was that the declaration was not entered because it was the same arguments as before, had insufficient evidence, and was merely an opinion.

CONCLUSION

Applicant respectfully requests entry of the foregoing remarks into the file of the above-identified application.

Respectfully submitted,

Date: January 4, 2010

 32,605  
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